

§ 868.2340 Compensated thorpe tube flowmeter.

(a) *Identification.* A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2350 Gas calibration flowmeter.

(a) *Identification.* A gas calibration flowmeter is a device intended for medical purposes that is used to calibrate flowmeters and accurately measure gas flow.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2375 Breathing frequency monitor.

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate is outside predetermined limits.

(b) *Classification.* Class II (performance standards).

§ 868.2380 Nitric oxide analyzer.

(a) *Identification.* The nitric oxide analyzer is a device intended to measure the concentration of nitric oxide in respiratory gas mixtures during administration of nitric oxide.

(b) *Classification.* Class II. The special control for this device is FDA's "Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric

Oxide Analyzer, and Nitrogen Dioxide Analyzer."

[65 FR 14465, Mar. 3, 2000]

§ 868.2385 Nitrogen dioxide analyzer.

(a) *Identification.* The nitrogen dioxide analyzer is a device intended to measure the concentration of nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide.

(b) *Classification.* Class II. The special control for this device is FDA's "Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer."

[65 FR 11465, Mar. 3, 2000]

§ 868.2450 Lung water monitor.

(a) *Identification.* A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any lung water monitor that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a lung water monitor that was in commercial distribution before May 28, 1976. Any other lung water monitor device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 65 FR 19834, Apr. 13, 2000]

§ 868.2480 Cutaneous carbon dioxide (PcCO₂) monitor.

(a) *Identification.* A cutaneous carbon dioxide (PcCO₂) monitor is a noninvasive heated sensor and a pH-sensitive glass electrode placed on a patient's skin, which is intended to monitor relative changes in a

§ 868.2500

hemodynamically stable patient's cutaneous carbon dioxide tension as an adjunct to arterial carbon dioxide tension measurement.

(b) *Classification*. Class II (performance standards).

[54 FR 27160, June 28, 1989]

§ 868.2500 Cutaneous oxygen monitor.

(a) *Cutaneous oxygen monitor for an infant patient who is not under gas anesthesia*—(1) *Identification*. A cutaneous oxygen monitor for an infant patient who is not under gas anesthesia is a device that uses a noninvasive sensor (e.g., a Clark-type polarographic electrode) placed on the patient's skin and that is intended to monitor relative changes in the cutaneous oxygen tension in an infant patient who is not under gas anesthesia.

(2) *Classification*. Class II (performance standards).

(b) *Cutaneous oxygen monitor for all other uses*—(1) *Identification*. A cutaneous oxygen monitor for all other uses is a device that uses a noninvasive sensor (e.g., a Clark-type polarographic electrode) placed on the patient's skin and that is intended to monitor relative changes in the cutaneous oxygen tension in a noninfant patient or in any patient, including an infant, who is under gas anesthesia.

(2) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 868.3.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987]

§ 868.2550 Pneumotachometer.

(a) *Identification*. A pneumotachometer is a device intended for medical purposes that is used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.

(b) *Classification*. Class II (performance standards).

21 CFR Ch. I (4–1–02 Edition)

§ 868.2600 Airway pressure monitor.

(a) *Identification*. An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.

(b) *Classification*. Class II (performance standards).

§ 868.2610 Gas pressure gauge.

(a) *Identification*. A gas pressure gauge (e.g., bourdon tube pressure gauge) is a device intended for medical purposes that is used to measure gas pressure in a medical gas delivery system.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2620 Gas pressure calibrator.

(a) *Identification*. A gas pressure calibrator is a device intended for medical purposes that is used to calibrate pressure-measuring instruments by generating a known gas pressure.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2700 Pressure regulator.

(a) *Identification*. A pressure regulator is a device, often called a pressure-reducing valve, that is intended for medical purposes and that is used to convert a medical gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]